REMARKS

Claims 1-12, 24, 26, and 28 have been cancelled in response to Examiner's rejection. New claims 30-35 are pending in the present application. No new matter is added by the addition of these claims. The basis for Claim 30 is found throughout the specification, and specifically at page 6, lines 8-9 and page 18, lines 5-7. The basis for Claims 31 and 34 is found in the specification at page 10, lines 33-36. The basis for Claims 32 and 35 is found at page 16, lines 33-36 of the specification. The basis for Claim 33 is provided throughout the specification, and specifically at page 6, lines 8-9 and 28-30 and page 18, lines 5-7.

35 U.S.C. Section 103(a) Rejection

The Examiner has rejected Claims 1-12, 24, 26 and 28, relating to a mucoadhesive composition, as being obvious in view of EP 733, 357 to Boltri et al, for the reasons stated on pages 2-5 of the Office Action dated September 24, 2001. Applicant has cancelled Claims 1-12, 24, 26 and 28 from the present application. Applicant submits new claims 30-35 related to methods of providing a mucoadhesive coating for consideration in the present application. Applicant respectfully traverses the rejection by the Examiner, as it may apply to the newly-presented method claims.

Before turning to the specific grounds of the rejection, it seems appropriate to briefly discuss the case law in support of Applicant's arguments for patentability. Turning to *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), it is well settled that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either within the cited reference or within the knowledge generally available to one of skill in the art, to modify the reference to reach the present invention. See also MPEP 706.02(j); MPEP 2142. In addition, the Patent Office must explain why a proposed modification of the art to arrive at Applicant's invention would be obvious. Ex parte Clapp, 227 USPQ 972, 973 (1985); MPEP 2142. The mere fact that the prior art may be modified as suggested by the Patent Office does not make the modification obvious unless the prior art suggests the desirability of the modification. See *In re Fritch*, 972 F.2d 1260, 23 USPQ 2d 1780 (Fed. Cir. 1992); MPEP 2144.08. Contrary to what seems to be the Examiner's position at Pages 3 and 4 of the Office Action, "[t]he fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish prima facie obviousness." MPEP 2143.01; see *Ex Parte Leavengood*, 28 USPQ 2d 1300 (1993).

Moreover, obviousness under 35 USC §103 requires that every claim element be taught or suggested by the prior art. MPEP 2143.03; *In re Royka* 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Notably the cited reference, Boltri, neither teaches nor suggests that compositions of the present type should be used in a dosage regimen that requires swallowing.

As a matter of law "[w]hen applying 35 USC §103, the following tenets of patent law must be adhered to: (1) the claimed invention must be considered as a whole including portions that would lead away from the claimed invention; (2) the reference must be considered as a whole and suggest the desirability and, thus, the obviousness of making the contribution; (3) the reference must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (4) reasonable expectation of success is the standard with which obviousness is determined." *Hodosh v. Block Drug Co., Inc.*, 786 F2d 1136, 1143, 229 USPQ 182, 187 (fed. Cir. 1986) [emphasis supplied]; MPEP 2141; MPEP 2141.02; and W.*L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 US 851 (1984); MPEP 2141.03. The question is not whether the difference between the prior art and the present claims would have been obvious, but whether the claimed invention as a whole would have been obvious in light of the prior art. See *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); MPEP 2141.02. In short, the "invention as a whole" test under 35 USC §103 requires the Examiner take into consideration the now-claimed invention with the specified swallowing step – a step not taught of suggested by the art of record – and the teaching of Boltri as a whole. See especially, MPEP 2141.02.

The present invention is directed to a method of providing a mucoadhesive coating to the mucosal tissue of the esophagus, stomach and small intestine by swallowing a mucoretentive, silica-containing composition. The compositions utilized in the present invention significantly thin when swallowed in order to achieve adequate spreading and coating of the gastrointestinal (GI) tract, which is essential for the swallowing step recited in the new claims. When these compositions contact the mucosal surface of the GI tract lining the viscosity of the compositions increases. Thus, after swallowing, the compositions herein mix with the fluids of the lining of the GI tract and the viscosity of the resulting mixture becomes greater than the viscosity of either the compositions or the GI fluids alone.

In addition to being mucoadhesive, it has been found that the compositions employed in the meth ds of the present invention exhibit mucoretention. That is, the compositions

provide resistance to peristalsis, as well as resistance to the washing and dissolving forces of fluids in the GI tract. Therefore, providing a mucoadhesive coating where an active agent is incorporated in the compositions achieves the additional benefit of sustained mucoretention and results in sustained release of those actives on the mucosa.

In sharp contrast with the present invention, the focus in Boltri is on a composition that will not leak once applied to an intended surface, yet is readily sprayable prior to application. *Boltri*, page 2, lines 20-21 and 8-13. To achieve this, Boltri teaches a nearly semi-solid, thixotropic, topical gel composition, comprising colloidal silica, an active ingredient, water and optional excipients. Boltri compositions must be sprayed and nebulized through the use of a mechanical pump to topically deliver an active agent to the intended area. *Boltri*, page 2, lines 3-4. After removal of the applied mechanical stress, the Boltri composition, being thixotropic, quickly returns to its near semi-solid or gelatinous state and pre-nebulization viscosity. Boltri only contemplates spraying of the compositions for topical application. One of skill in the art would expect that, if sprayed in the mouth, the compositions would gel prior to and during swallowing. One would expect such compositions to be difficult to swallow and have the potential to cause gagging. Thus, one would not expect that a thixotropic formulation as described by Boltri would have acceptable aesthetics for use in a treatment regimen that requires swallowing. Boltri, therefore, does not fairly teach or suggest swallowing the compositions disclosed therein.

In short, Boltri teaches only topical administration by spraying to areas on which direct application and no spreading of his compositions is desired. Boltri expressly states that the compositions are applied to areas where *in loco persistence* is of particular importance. *Boltri*, page 3, lines 15-17. There is simply no suggestion that Boltri's compositions should, or could, be administered to the esophagus, stomach and small intestine by swallowing. Boltri lists only the skin, the ear, the vaginal cavity, and the nasal cavity as the areas where such compositions are useful. *Id.* In contrast, the present invention requires spreading and coating of the liquid compositions on the GI mucosa upon swallowing to ensure that a mucoahesive coating is provided thereon. Boltri does not discuss mucoadhesion at all. Thus, it cannot be said that Boltri teaches or suggests a method for providing a mucoadhesive coating on the GI mucosa.

To summarize: In Boltri there is no teaching or suggestion that swallowing is an acceptable form of administration for the compositions disclosed therein and, more importantly, there is no suggestion that the compositions therein could be used to provide a

mucoadhesive coating. The Applicant has discovered that through the step of swallowing, such compositions provide a mucoadhesive coating on the mucosa of the gastrointestinal tract, specifically the esophagus, stomach and small intestine. Boltri does not recognize this use for silica-containing compositions as Boltri does not contemplate swallowing or mucoadhesive coating at all.

It is submitted that nothing in the Boltri reference teaches or suggests the use of the disclosed compositions by swallowing them in the manner of the present invention. It is settled case law that the question of obviousness under §103 is not what the artisan could have done, but what would have been obvious for the person to do. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ 2d 1081 (Fed. Cir. 1986). Finally, it is again noted that the reference does not suggest every element of the claims – to wit, the swallowing step. Accordingly, the reference does not render the claims obvious under 35 USC §103. MPEP 2143.03 and In re Royka, ibid.

CONCLUSION

Based on the above amendments, arguments and facts, all rejections or objections are traversed or avoided. Applicants respectfully request withdrawal of all rejections and allowance of all the claims.

Respectfully submitted for
DOUGLAS J. DOBROZSI

By Andrea L. Winslow
Andrea L. Winslow
Agent for Applicants
Registration No. 48,586
(513) 622-1822

December 20, 2001
The Procter & Gamble Company
Health Care Research Center (Box 1050)
P.O. Box 8006
Mason, OH 45040-8006